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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/803,954 | 02/21/1997 | KEITH E. LANGLEY | 0109063/004 | 9382 |

7590 01/15/2002

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[REDACTED] EXAMINER

HAYES, ROBERT CLINTON

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1647

DATE MAILED: 01/15/2002

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|---|--------------------------------------|
| Application No. 08/803,954 | Applicant(s) Langley et al |
| Examiner Robert C. Hayes, Ph.D. | Art Unit 1647 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Dec 3, 2001
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 53-67 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 53-67 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 8/29/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/803954 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restriction

2. Newly submitted claims 53-67 are directed to an invention that is independent or distinct from the invention originally claimed, which include claims to previously nonelected Group III (i.e., see Paper No. 4), as well as claims directed toward other new independent and distinct inventions. It is noted that previously elected and prosecuted Group I (claims 1-11, 28-29, 31-32 & 37) was directed toward metalloproteinases inhibitor polypeptides. All claims to the originally elected invention in Paper No. 6, which was elected **without** traverse, have now been cancelled (e.g., see Paper No. 10).

3. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

III. Claims 53-56, drawn to antibodies to a polypeptide having metalloproteinase inhibitor activity, as well as hybridoma cells that produce such, classified in Class 530, subclass 387.1, and Class 435, subclass 331.

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IV. Claims 57-67, drawn to methods of detecting polypeptides having metalloproteinase inhibitor activity in biological samples, and kits therefor, classified in class 435, subclass 7.1.

4. The inventions are distinct, each from the other because of the following reasons:
Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies and hybridoma cells of Group III can be used in other materially different diagnostic or therapeutic methods, such as treating patients or in methods to purify proteins by affinity chromatography. In contrast, the method of Group IV to detect a metalloproteinase inhibitor requires radioimmunoassays, enzyme-linked immunoassays, or label itself, which is not necessarily required in the products of Group III. Additionally, the hybridomas of Group III are not required in the method of Group IV, and vice versa. Therefore, the groups are distinct as indicated.

5. Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner

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to search and consider all the separable groups with their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

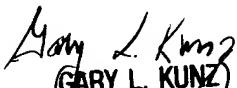
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Robert C. Hayes, Ph.D.
January 14, 2001


GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600